MAY 2 3 2006

K061175
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510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: SOTA PRECISION OPTICS, INC
2-Address: 1073 NORTH BATAVIA STREET, ORANGE, CA 92867
3-Phone: (714) 532-6100
4-Fax: (714) 532-6107
5-Contact Person: Mr Brian Kim (President)
6-Date summary prepared: April 14th, 2006
7- Official Correspondent for this 510k submission: Jay Mansour, Mansour Consulting LLC
8- Address: 845 Aronson Lake Court, Roswell, GA 30075
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12-Device Trade or Proprietary Name: Claris i310D
13-Device Common or usual name: Intraoral camera system and accessories
14-Device Classification Name: Unit, Operative, Dental
15-Substantial Equivalency is claimed against the following device:

- Claris i310 from SOTA PRECISION OPTICS, INC.
  510k# K032341

16-Description of the Device: (For technical specifications, refer to the user manual) (Full listing and photos of accessories is available within this submission- refer to user manual)

Claris i310D comprises of a light (0.1 lbs), small (8.3" x 0.85"), and ergonomic handpiece.

The handpiece consists of a focusing mechanism and a capture button to assist the doctor in taking intraoral or full face images of the patient.

The handpiece connects to the computer via USB 2.0 port.

A cradle is provided to allow for on-off functions.

Claris i310D has a digital resolution (720x480 pixels) to capture images at 60 degrees field of view. Images may be stored using third party software vendors.

17-Intended use of the device: (refer to FDA form attached)

Claris i310D intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results.

18-Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 19 below)

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19-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K032341
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Similar
Sterility	Identical (being not applicable as well)
Biocompatibility	Identical
Mechanical safety	Similar
Chemical safety	Identical (being not applicable as well)
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Similar
Radiation safety	Similar

Refer to the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2006

Sota Precision Optics, Incorporated
C/O Jay Mansour
Mansour Consulting, LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K061175
Trade/Device Name: Claris i310D Intra Oral Camera System and Accessories
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: April 14, 2006
Received: April 27, 2006

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

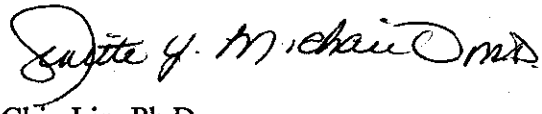
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061175

Device Name: Claris i310D Intra Oral Camera System and accessories

Indications For Use:

Claris i310D intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K061175